PATENT COOPERATION TREATY HT2 RSD CMC

LVM 702038 HGSI

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	29 MAY 2009

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
7054846001	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US06/38756	05 October 2006 (05.10.2006)	13 October 2005 (13.10.2005)

Applicant

HUMAN GENOME SCIENCES, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

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JUN 03 2009

PAY/TM Due Date

Name and mailing address of the IPEA/US	Authorized officer
Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	brian johnson
Facsimile No. (571) 273-3201	Telephone No. 571-272-2100

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 7054846001	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US06/38756	International filing date *(day/month/year)* 05 October 2006 (05.10.2006)	Priority date *(day/month/year)* 13 October 2005 (13.10.2005)
International Patent Classification (IPC) or national classification and IPC IPC: Please See Continuation Sheet USPC: 435/69.1;536/23.5;530/387.1;424/139.1,9.1		
Applicant HUMAN GENOME SCIENCES, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

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Date of submission of the demand	Date of completion of this report
10 July 2008 (10.07.2008)	13 May 2009 (13.05.2009)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer STACEY MACFARLANE Telephone No. (571) 272-1600

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/38756

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3(a) and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-165 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the claims:
pages 166-171 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the drawings:
pages 1/1 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US06/38756

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-69	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-69	NO
Industrial Applicability (IA)	Claims 1-69	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 35-55 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 35-55 are indefinite for the following reason(s): the claims fail to recite the active method steps by which to determine a reduction in the frequency or quantity of corticosteroid use of a patient. Reduction is a relative term and the requisite degree by which the reduction is ascertained is not put forth within the claim, nor does the specification recite any guidance as to how an artisan would practice the method.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US06/38756

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☒ on paper

   ☒ in electronic form

   c. time of filing/furnishing

   ☒ contained in the international application as filed

   ☒ filed together with the international application in electronic form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* *If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*

Supplemental Box

titers typically >1:80.

Claims 1, 18-19. 21-34 and 56-69 lack an inventive step under PCT Articlg 33(3) as being obvious over BRAM et al., RUBEN et al.,GROSS et al. (2000) and GROSS et al. (2002) as applied to claims 1-19 in view of Arthritis and Rheumatism, Volume 50(11), November 2004, pages 3418-3426. Claims are drawn to a method of treating a patient that has an ANA titer > 1:80 comprising administering a therapeutically effective amount of an antagonist of Neutrokine-alpha, wherein the patient has a SELENA-SLEDAI score > 6. While the BRAM et al., RUBEN et al. GROSS et al. (2000) and GROSS et al. (2002) each teach methods of treating patients comprising an embodiment of an antagonist of Neutrokine-alpha, they do not teach methods further comprising measuring a SELENA-SLEDAI score of> 6. The Arthritis and Rheumatism article, published by the American College of Rheumatology Ad Hoc Committee on SLE Resonse Criteria, states that it was well-known within the art to characterize lupus patients according to their SELENA-SLEDAI score. As Tables 2 and 3 of the reference demonstrate, subjects typically display a SELENA-SLEDAI score that are greater than 6. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of the references in order to better characterize the patient according to known methods.

Claims I, 3, 15, 13-15, 18 and 20 lack an inventive step under PCT Article 33(3) as being obvious over BRAM et al., RUBEN et al. GROSS et al. (2000) and GROSS et al. (2002) as applied to claims 1-19 in view of LOONEY R.J. Rheumatology, Volume 44, Supplement 2, pages ii 13-iii 7, published May 2005. Claims are drawn to a method of treating a patient that has an ANA titer > 1:80 comprising co-administering an anti CD20 antibody. While the BRAM et al., RUBEN et al. GROSS et al. (2000) and GROSS et al. (2002) each teach methods of treating patients comprising an embodiment of an antagonist of Neutrokine-alpha, they do not teach methods further comprising administering an anti-CD20 antibody. However, the LOONEY reference teaches that it was well-known in the art prior to filing that anti-CD20 therapy was useful to treat a variety of refractory autoimmune diseases. Therefore, it would have been obvious to a skilled artisan to combine the teachings of the prior art.